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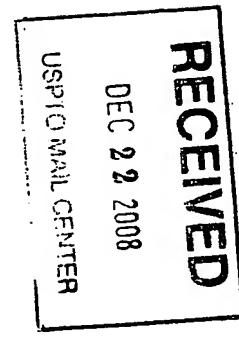
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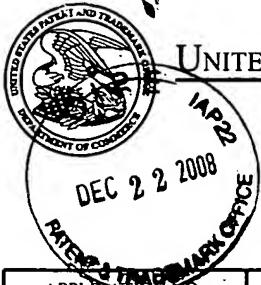
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TJW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,232	03/23/2006	Philippe G. Nantermet	21546YP	5429
210	7590	12/17/2008	EXAMINER	
MERCK AND CO., INC			WARD, PAUL V	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07065-0907			1624	
MAIL DATE		DELIVERY MODE		
12/17/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/573,232	NANTERMET ET AL.
	Examiner PAUL V. WARD	Art Unit 1624

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 September 2008.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9, 12-19, 21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-9, 12-19 and 21 is/are allowed.
- 6) Claim(s) 23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/06 3/23/06</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on September 22, 2008 is acknowledged. The traversal is on the ground(s) that the unity of invention requirement is met by the structure shown in Figure I. This is not found persuasive because The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is drawn to a compound, its composition and method of use. Group II is a different compound with respect to the compound of Group I. Therefore, there is no special technical feature for the compounds or different fields of application of the compounds. Additionally, there is no unity of invention.

There is no special technical feature, which unites the groups. But even if there were a special technical feature there must be unity of invention also. Under 37 CFR 1.475:

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features"

shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
- (1) A product and a process specially adapted for the manufacture of said product; or
  - (2) A product and a process of use of said product; or
  - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
  - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
  - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The above groups 1-2 together do not meet the requirement of unity of invention as given above in (1) -(5).

The requirement is still deemed proper and is therefore made FINAL.

Applicant is entitled to have the method Groups rejoined under M.P.E.P. § 821.04, if the claims of Group I are ultimately found allowable.

Groups II-XX are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement, and reserved the right to file a divisional application to the non-elected subject matter.

An action on the merits on claims 1-9, 12-19, 21 and 23 is contained herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 23 is directed to a method of treating Alzheimer's disease. The term is interpreted to include any and all forms Alzheimer's disease including inhibiting gamma secretase and deposition of beta amyloid protein. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types/forms of Alzheimer's disease.

In re Hozumi, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

The breadth of the instant claims is seen to encompass methods for treating of Alzheimer's disease by administering to a patient in need of such treatment a therapeutically effective amount of the compound claim. Applicant failed to exactly defined how Alzheimer's disease, inhibiting gamma secretase and deposition of beta amyloid protein are treated. Thus, the claim is extremely broad.

**The nature of the invention**

The nature of the invention is the treatment of Alzheimer's and through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat Alzheimer's including inhibiting gamma secretase and deposition of beta amyloid protein all inclusively.

**The level of predictability in the art**

The treatment of Alzheimer's is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

**The amount of direction provided by the inventor.**

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of Alzheimer's claimed. Further, the applicant discloses that an effective amount of the compound will be administered (see specification) without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

**The existence of working examples.**

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating Alzheimer's. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment and methods in inhibition. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating with the claimed compound.

**The level of one of ordinary skill.**

The level of skill is that of one with a doctoral understanding of Alzheimer's and neurodegenerative diseases therapeutics. Applicants claim a method of treatment for Alzheimer's disease, this disease is a very hard to treat. The central characteristic of Alzheimer's disease is the deficiency in the level of the neurotransmitter Acetylcholine that plays an important role in memory. Alzheimer's Disease is an extraordinarily difficult disease to treat, and has been the subject of a vast amount of research. Despite an enormous number of different approaches, the skill level in the art is so low relative to the difficulty of task that the only success has come from treatment by compounds such as Acetylcholinesterase inhibitors (Aricept®, Cognex®, Exelon®, and Reminyl®), a property not disclosed in Applicant's compounds.

Furthermore, there is no evidence that the inhibition of amyloid B-peptide production for the treatment of Alzheimer's disease has ever been accomplished. For example, Golde teaches that at least one group has used gamma-secretase inhibitors in an animal model to lower the levels of B-amyloid in the brain and that at lease one gamma-secretase inhibitor has gone to clinical trials. (See J. Clin. Invest. 111:11-18 (2003) at page 13). However, Golde makes clear that the actual treatment of the condition of Alzheimer's based upon inhibition of gamma-secretase is still being developed and that identification of an inhibitor is not enough. Golde also lists several problems with regard to undesirable pleitropic effects that must be addressed prior to development of an actual treatment. (See page 13, col. 2). Applicant's system fails to address the problems of undesirable pleitropic effects, and thus, it appears that while gamma-secretase may be a viable drug target in the future, considerable future

research needs to be done. In view of the Golde reference, Applicant's data is not convincing as to make the production and use of pharmaceutical compositions comprising the recited compounds feasible without undue, un-predictable experimentation.

**The quantity of experimentation.**

A great deal of experimentation is required. In order for there to be a method of treating Alzheimer's disorders generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of Alzheimer's and neurodegenerative. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of Alzheimer's and neurodegenerative diseases with the claimed compound individually or in combination with other therapeutic agents. Moreover, in view of the level of one of ordinary skill, since the inhibition of A $\beta$ -peptide production for the treatment of Alzheimer's disease has never been accomplished, no guidance from the success of others is available from this experimentation.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment of Alzheimer's disease.

***Allowable Subject Matter***

Claims 1-9, 12-19 and 21 are allowed. The prior art does not teach any of the benzylether and benzylamino compounds of Group I, wherein R<sub>1</sub> is phenyl or naphthyl, substituted in the manner claimed by the Applicant. Thus, the compounds in Group I were neither found to be obvious nor anticipated by the prior art of record. The prior art does not teach or suggest the presently claimed compound.

***Conclusion***

Claims 1-9, 12-19, 21 and 23 are pending. Claim 23 is rejected. Claims 1-9, 12-19 and 21 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/PAUL V WARD/  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination NANTERMET ET AL.	
		Examiner PAUL V. WARD	Art Unit 1624	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	Golde, T.E. "Alzheimer disease therapy: Can the amyloid cascade be halted?", J'nal of Clinical Investigation, Jan' 2003, Vol. 111, No. 1, pp. 11-16.
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**10/573232**

**IAP20 Rec'd PCT/PTO 23 MAR 2006**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Philippe G. Nantermet	
Serial No.:	To Be Assigned	Case No.: 21546YP
US Nat'l Filing Date:	March 23, 2006	
Int'l Appl'n No.	PCT/US2004/032009	
Int'l Filing Date:	September 29, 2004	
For:	BENZYLETHER AND BENZYLAMINO BETA-SECRETASE INHIBITORS FOR THE TREATMENT OF ALZHEIMER'S DISEASE	

MAIL STOP PCT  
Commissioner for Patents  
P.O. BOX 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR § 1.97**

Sir:

In compliance with 37 CFR § 1.97, Applicants and other individuals associated with the filing or prosecution of this application wish to bring to the attention of the Examiner the patents, publications, and other information of which they are aware, listed on the attached form PTO-1449, which they believe may be relevant to the examination of this application or may be material to patentability and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56. Applicants respectfully request that the Examiner initial the form PTO-1449 after reviewing the pertinence of each reference.

**EXPRESS MAIL CERTIFICATE**

DATE OF DEPOSIT March 23, 2006  
EXPRESS MAIL NO. EL 98958539316

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail "Post Office to Addressee" on the above date in an envelope addressed to:

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Alexandria, Virginia 22313-1450

MAILED BY Kathy Kluttselle  
DATE 3-23-06

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.W./

**10/573232**

Int'l Appl'n No.:

PCT/US2004/032009

Case No.:

21546YP

Patent:

**IAP200400PCT/P023 MAR 2006**

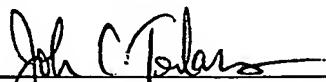
This Information Disclosure Statement is not an admission that any patent, publication, or other information referred to herein is "prior art" for this invention.

References A and B on the accompanying PTO 1440 form were cited in the International Search Report for this application. A copy of the International Search Report and Written Opinion are enclosed with this Information Disclosure Statement.

In accordance with 37 CFR § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b). In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made.

Pursuant to 37 CFR § 1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the present application. Accordingly, it is believed that no fee is due. Any additional fees required in connection with this submission may be taken from Merck Deposit Account No. 13-2755.

Respectfully submitted,

By   
John C. Todaro, Reg. No. 36,036  
Attorney for Applicant

MERCK & CO., Inc.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
(732) 594-0125

Date: March 23, 2006

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.W./

Substitute for form 1449A/PTO				<b>COMPLETE IF KNOWN</b>	
<b>INFORMATION DISCLOSURE</b>				Application Number	To Be Assigned <b>10/573232</b>
<b>STATEMENT BY APPLICANT</b>				Filing Date	March 23, 2006
(use as many sheets as necessary)				First Named Inventor	Philippe G. Nantermet
Sheet	1	of	1	Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
				Attorney Docket Number	21546YP

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
D		WO 89/04833		PCT	The Upjohn Company	06/01/1989
E		WO 01/00665		PCT	Oklahoma Medical Research Foundation	
					& Board of Trustees of the Univ. of Illinois	01/04/2001
F		WO 2003/072535		PCT	Elan Pharmaceuticals and Pharmacia	
					& Upjohn Company	09/04/2003
G		WO 02/02512		PCT	Elan Pharmaceuticals and Pharmacia	
					& Upjohn Company	01/10/2002

**Examiner  
Signature**

/Paul Ward/ (12/13/2008)

**Date Considered**

**ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. P.W./**

**SEND TO:** Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Philippe G. Nantermet et al.	
Serial No.:	10/573,232	Case No.: 21546YP
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Int'l Filing Date:	29 September 2004	
For:	BENZYLETHER AND BENZYLAMINO BETA-SECRETASE INHIBITORS FOR THE TREATMENT OF ALZHEIMER'S DISEASE	

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UNDER 37 CFR § 1.97

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I hereby certify that this correspondence is being deposited with the United States Postal Services as first class mail in an envelope addressed to:  
Commissioner for Patents, P. O. Box 1450,  
Alexandria, VA 22313-1450, on the date appearing  
Below.

MERCK & CO., INC.

*[Handwritten signature]* Date *June 21, 2006*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.W./

Int'l Appl'n No.: PCT/GB2004/032009  
Case No.: 21546YP  
Page 2

This Information Disclosure Statement is not an admission that any patent, publication, or other information referred to herein is "prior art" for this invention.

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Respectfully submitted,

By John C. Todaro  
John C. Todaro, Reg. No. 36,036  
Attorney for Applicant

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Date: June 21, 2006

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.W./

Substitute for form 1449A/PTO		<b>COMPLETE IF KNOWN</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		Application Number <b>10/573,232</b> Filing Date <b>March 23, 2006</b> First Named Inventor <b>Philippe G. Nantermet</b> Group Art Unit <b>To Be Assigned</b> Examiner Name <b>To Be Assigned</b> Attorney Docket Number <b>21546YP</b>			
Sheet	1	of	1		

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

**Examiner Signature** /Paul Ward/ (12/13/2008) **Date Considered**

**RELEVANT REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH**